

MAY 16 2000

510(k) Summary of Safety and Effectiveness

K00143A

**Somnus Medical Technologies, Inc.
Model S2 Electrosurgical Generator**

Intended Use:

The Somnus® Modified Model S2 Electrosurgical Generator is intended for use with the Somnus Disposable Soft Tissue Coagulating Electrodes for the coagulation of soft tissue. The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Submitted by:

Somnus Medical Technologies, Inc.
285 North Wolfe Road
Sunnyvale, CA 94086
Tel: 408-773-9121
Fax: 408-773-9137

Contact Person:

Steven J. Ojala, Ph.D.
Vice President of Clinical, Quality
and Regulatory Affairs
Tel: (408) 617-3434

Date Summary Prepared::

May 2, 2000

Name of the Device:

Proprietary Name:	Somnus® Model S2 Electrosurgical Generator
Common/Usual Name:	Electrosurgical Generator and Accessories
Classification Name:	Electrosurgical Device (per 21 CFR 878.4400)

Predicate Devices:

Somnus Model S2 (K 970576) (cleared as Model 615)

Description:

The Somnus Model S2 Electrosurgical Generator has controls for maximum temperature, energy delivered, maximum power, and time of energy delivery. The unit has readouts for total power delivered, impedance, maximum power, time countdown, and temperature for up to 18 thermocouples. Connectors on the front panel include connector for active

electrode and dispersive electrode. The footpedal is connected on the front panel.

Accessories included with the generator are a line power cable and a pneumatic pedal footpedal.

Statement of Intended Use:

The Somnus Model S2 Electrosurgical Generator is intended for use in the coagulation of soft tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Devices:

The Somnus Modified Model S2 Electrosurgical Generator has been carefully compared to the legally marketed Somnus Model S2 with respect to intended use and technological characteristics. In addition, performance validation testing has been done to validate the performance of the device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 16 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Steven J. Ojala, Ph.D.
Vice President of Clinical, Quality
and Regulatory Affairs
Somnus Medical Technologies, Inc.
285 North Wolfe Road
Sunnyvale, California 94086

Re: K001438
Trade Name: Somnus Modified Model S2 Electrosurgical Generator
Regulatory Class: II
Product Code: GEI
Dated: May 5, 2000
Received: May 8, 2000

Dear Dr. Ojala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Not yet assigned.

K001438

Device Name:

Somnus® Model S2 Electrosurgical Generator

Indications for Use:

The Somnus Model Electrosurgical Generator, in combination with various Somnus disposable tissue coagulating electrodes, is indicated for the coagulation of tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Contraindications for Use:

The use of the Somnus Model S2 Electrosurgical Generator is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interests of the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ____
(Optional Format 1-2-96)

Dan R. Vachner
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K001438